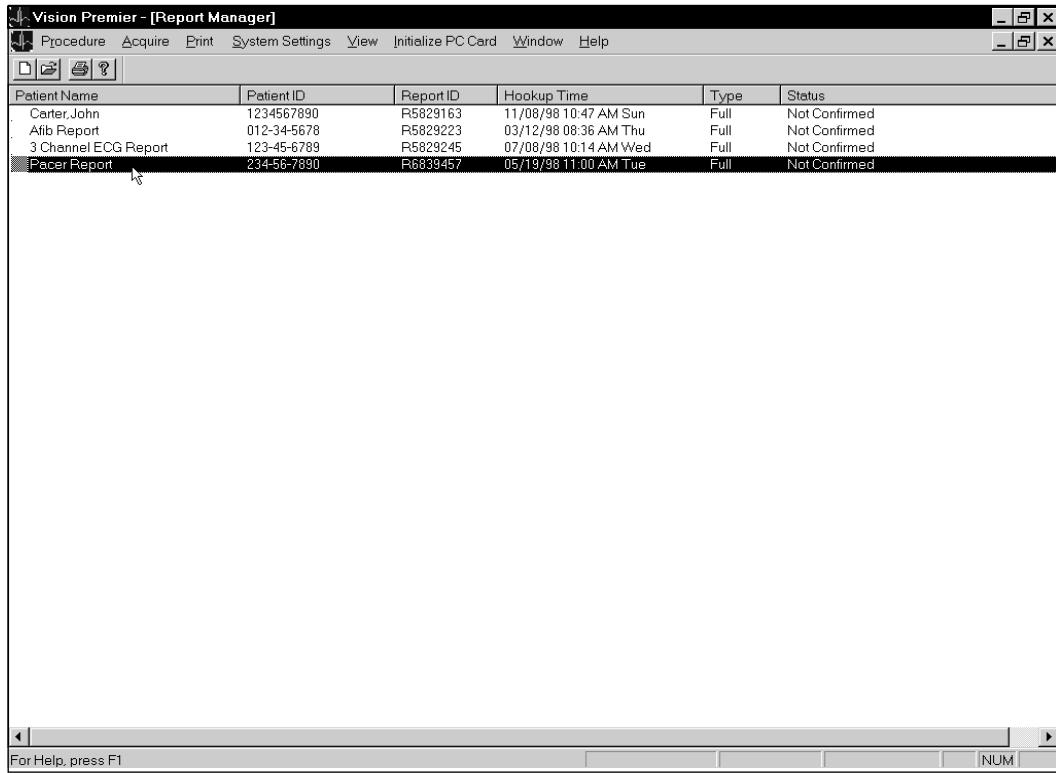


Operating Instructions



Vision™ Series Pacer Software Option

Operating Instructions Part No. 086558-PA
Revision: 0103

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Burdick, Inc.
500 Burdick Parkway
Deerfield, Wisconsin 53531 U.S.A.
(800) 777-1777 (608) 764-1919

Authorized EC Representative
Medical Device Safety Service, GmbH
Burckhardtstr. 1
D-30163 Hannover
GERMANY

Contact: Ludger Moeller
E-mail: lmoeller@mdss.com
Telephone: +49 511 62628630
Fax: +49 511 62628633

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Intended Use

The Pacer Analysis module is an optional software feature that enables the Vision™ Series Holter Analysis systems to analyze pacemaker information recorded by Burdick digital recorders.

These operating instructions are intended to supplement operating instructions provided with the Vision™ and Vision Premier™ Holter Analysis Systems.

Pacemaker information is used by the analysis program to classify beats compiled during data collection as paced. Once the system has completed this analysis, a tabulated report can be displayed and printed making it easy for you to review and edit the analyzed data.

Capabilities

Disk Recorder Upload

During the process of uploading patient information into the disk recorder, pacer spike information is automatically uploaded as well. This information is later analyzed by the pacer software.

Automatic Analysis of Pacer Spike Information

The pacer analysis program uses the pacer spike information collected during the disk recorder upload process to re-classify beats as paced. For a beat to be labeled as "P" for paced, the pacer spike must occur in a window that is 250 msec to -50 msec from the beat's fiducial point. Pacer spikes occurring 250 to 150 msec prior to the beat's fiducial will be classified as atrial paced. Pacer spikes occurring 150 to -50 msec from the beat's fiducial will be classified as ventricular paced. Any beats with both atrial and ventricular pacer spikes will be classified as dual. The pacer program will maintain the count of paced beats classified as atrial, ventricular and dual.

All paced beats will be grouped together into individual forms based on the clustering algorithm.

Electronic Manuals

Vision Series software includes electronic manuals, if this optional feature has been installed. To access electronic manuals, including the Vision Series Setup Guide, Operating Instructions, Pacer Opacting Instructions, HRV Operating Instructions, and Holter recorder Operating Instructions, perform the following steps:

1. From the Windows desktop, double-click the program icon.
This will start the program.
2. Under Help on the menu bar, select Setup Guide or one of the other manuals that are listed.

NOTE: The Operating Instructions is listed as Main Manual.

Installing the Program

NOTE: The Vision Series Setup Guide contains additional information, including requirements, for installing and removing software and licenses.

Install License

NOTE: If you are installing the license onto a computer with Windows 95 or Windows 98 Second Edition, then you must follow the instructions under “Configure Environment Variables” on pg. 1-4 prior to installing the license.

1. Insert the license CD into the CDR drive.
2. Click on Start in the lower left corner on the screen.
3. Click Run.
4. Click [Browse] to locate **X:\install_license.bat** (where **X:** is the drive designator for the CDR drive).
5. Click install_license.bat.
6. Click [Open].
7. Click [OK]. The License software will install onto your system. When the License installation is complete, the system returns to the Windows® desktop.
8. Press the eject button on the CDR drive. The Adaptec DirectCD Wizard appears.
9. Ensure that the Leave the disc as it is... option is selected.

CAUTION: *Selecting any other option may result in damage to the license CD.*

10. Click [Finish] and remove the CD disk from the CDR drive.

Remove License

Follow the instructions under “Install License” above. For step 4 and step 5, locate and select the file **remove_license.bat**.

Configure Environment Variables

If you are installing onto a computer with Windows 95 or Windows 98 Second Edition operating system, then complete the following steps below before installing the license.

1. Click **Start** in the lower left corner on the screen.
2. Click **Run**.
3. Type the following: **edit c:\config.sys**
4. Click **[OK]**. A text editor displays the contents of the config.sys file.
5. Scroll to the end of the file. If the following text does not appear, add it to the end of the file:
SHELL=C:\WINDOWS\COMMAND.COM C:\WINDOWS /P /E:2048
6. Click **File** and select **Save**.
7. Click **File** and select **Exit**.
8. Restart the computer.

Prior to hooking the patient up to the recorder and acquiring data, the Pacer Detection Sensitivity must be set. The Pacer Detection Sensitivity is set during the PC Card initialization process. Refer to "Recorder Preparation" in the Vision™ or Vision Premier™ Operating Instructions for PC Card initialization procedures.

When the *Initialize PC Card* window appears, click the desired Pacer Detection Sensitivity radio buttons.

- ✓ Disable Detection-Recommended on a patient who has no pacemaker.
- ✓ Standard Sensitivity-Recommended for use with a unipolar type pacemaker or on a patient who has no pacemaker.
- ✓ High Sensitivity-For use with a bipolar type pacemaker when there is a high level of interference.
- ✓ Maximum Sensitivity-For use with a bipolar type pacemaker.

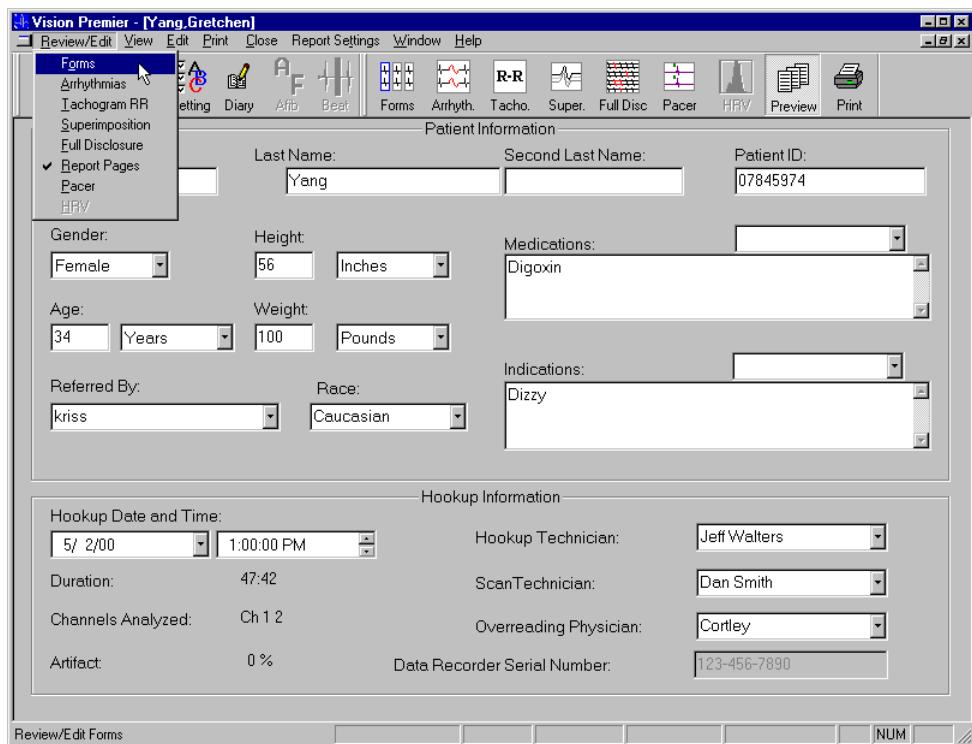
NOTE: The above recommendations for sensitivity selection should be used only as a guideline. Increasing sensitivity may result in false detection of pacer spikes due to signal noise. Ideally, maximum sensitivity should be used in all cases where pacemaker type is unknown, or where optimum pacer spike capture is desired.

Upon completion of the PC Card initialization process, the PC Card will be ready for data acquisition.

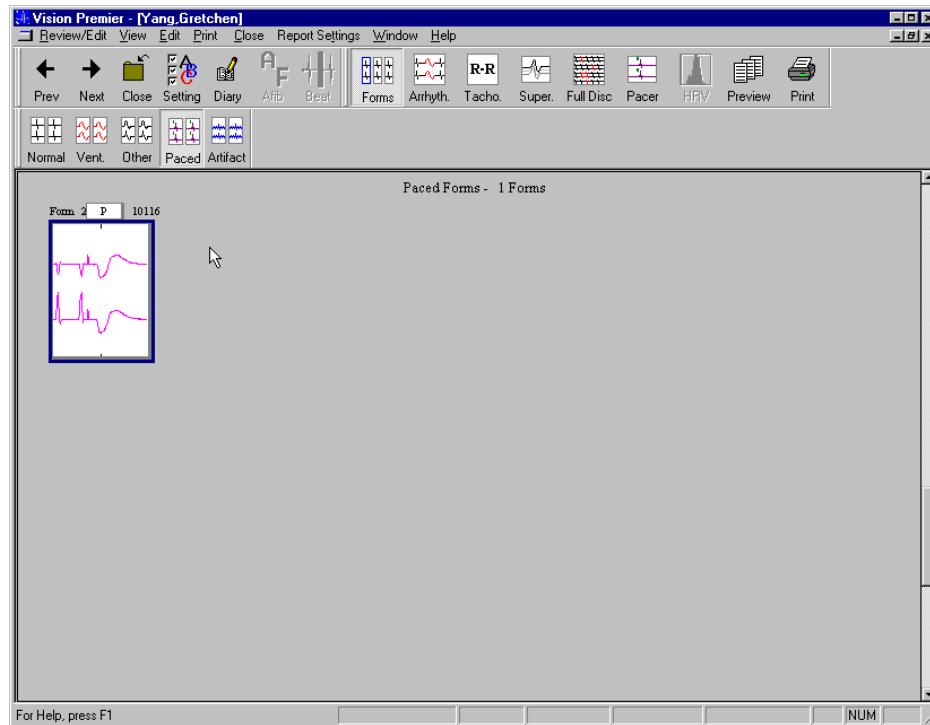
When analysis is complete, you have a variety of options for viewing and editing pacer spike information. These options are available when the report is open.

Review Forms

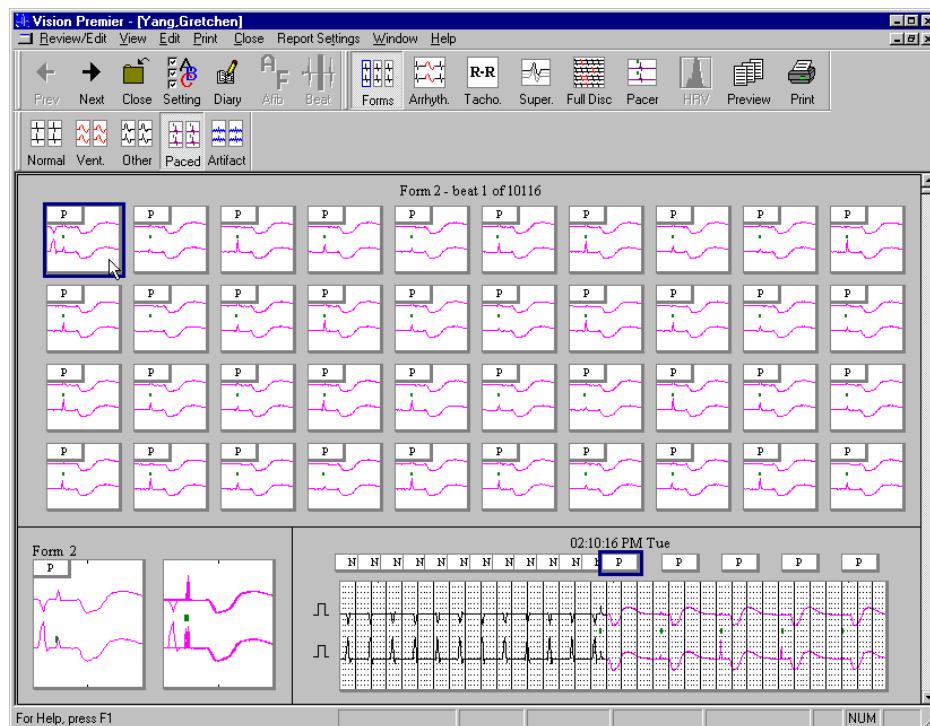
1. To access the paced forms, click on the Review/Edit menu option, then click on the Forms menu option.



2. To review the Paced forms, click on the scroll bar arrow until the until Paced Forms screen appears.



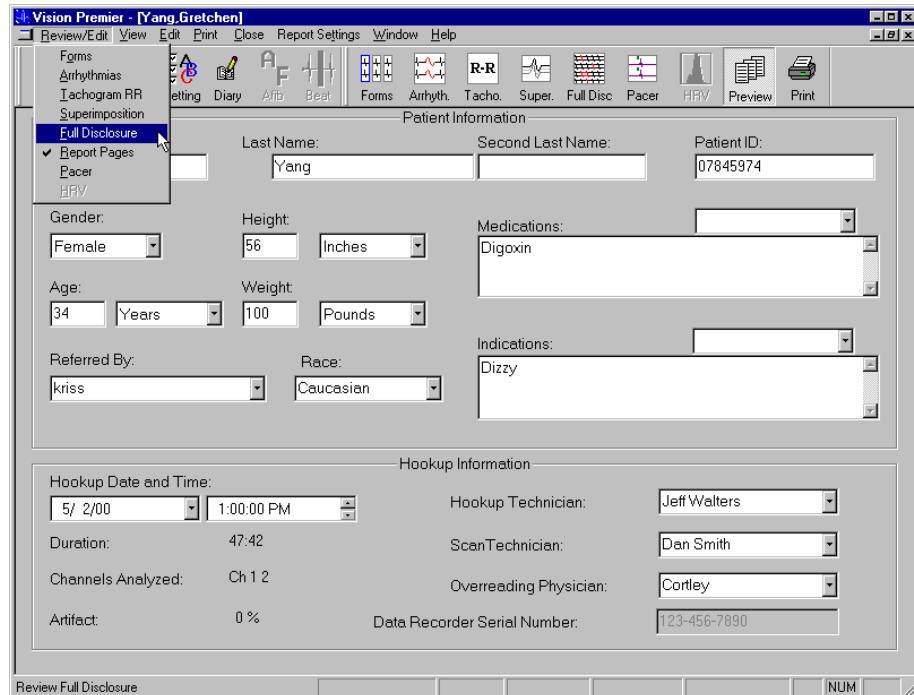
3. To display the beats in a form, double-click on that form. The paced beats will be magenta on a color monitor.



In this mode, you can edit beats that have been mislabeled by right clicking on the beat label. A menu will appear from which you can select a different beat label.

Full Disclosure

- To access full disclosure, click on the Review / Edit menu option, then click on the Full Disclosure option.



- The Full Disclosure screen displays strips of beats compiled during data collection. Click on the vertical scroll bar until you see beats displayed in magenta with a green indicator above the beat. The Pacer software has categorized these magenta beats as paced. The green marker indicates the location of the pacer spike detected.



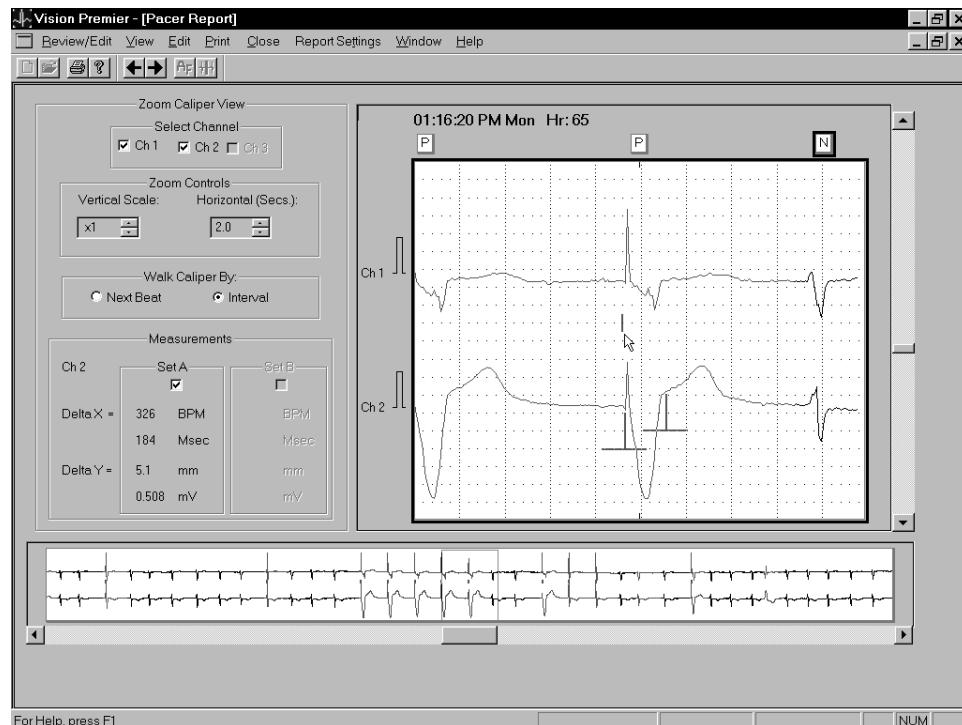
3. The Diagnostic Strip view displays a close-up of the beats located in the rectangle. To access Diagnostics Strips, click on the View menu option, then click on the Diagnostic Strip option.



The paced beats are marked with a small green rectangle above ECG channel 3. If two channel ECG is displayed the small green rectangle will be above ECG channel 2.

NOTE: Calipers view is only available with the Vision Premier™ system.

4. The calipers view displays an even more close-up view of the beat. To access Calipers, click on the View menu option, then click on the Calipers option.

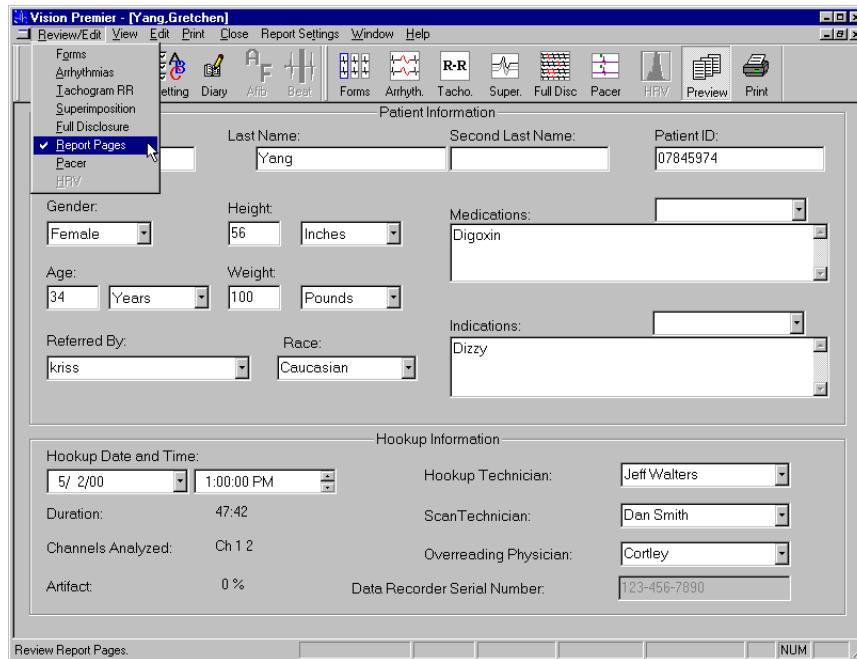


A small green rectangle identifies the location of the detected pacer spike.

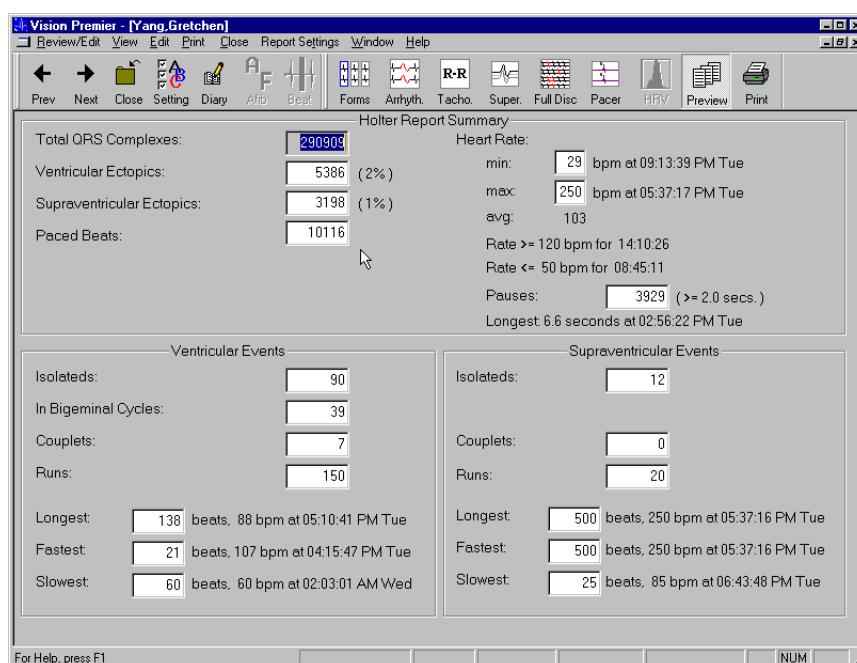
Review Report

Among the many report pages available to you, there are two pages that contain pacemaker information.

- To access the report pages, click on the Review/Edit menu option, then click on the Report Pages option.



- Using the Previous Page and Next Page toolbar buttons, review the different pages of the report. Click on the Next Page toolbar button to display the Holter Report Summary Page. Along with other information, this screen displays the number of paced beats in the report.



3. Click on the Next Page toolbar button to display the Pacemaker Summary page. This screen displays an hourly breakdown of the total number of QRS complexes, the total number of paced beats and the percentage of paced beats that were recorded hourly.

The screenshot shows the 'Pacemaker Summary' table with the following data:

Time	QRS			Paced			Operator			Failure To		
	Total	Total	%	Atrial	Ventricular	Dual	Paced	Sense	Capture	Fire		
1 Tue	4121	0		0	0	0	0	0	0	0		
2	5915	3600	61	3600	0	0	0	0	0	0		
3	4852	0		0	0	0	0	0	0	0		
4	3473	100	3	100	0	0	0	0	0	0		
5	3655	0		0	0	0	0	0	0	0		
6	3406	0		0	0	0	0	0	0	0		
7	9834	0		0	0	0	0	0	0	0		
8	8076	0		0	0	0	0	0	0	0		
9	6590	0		0	0	0	0	0	0	0		
10	4484	0		0	0	0	0	0	0	0		
11	8867	0		0	0	0	0	0	0	0		
12 Wed	11151	0		0	0	0	0	0	0	0		
1	4382	383	9	383	0	0	0	0	0	0		
2	11597	0		0	0	0	0	0	0	0		
3	6084	0		0	0	0	0	0	0	0		
4	4162	0		0	0	0	0	0	0	0		
5	11456	0		0	0	0	0	0	0	0		
6	8575	0		0	0	0	0	0	0	0		
7	3405	975	29	975	0	0	0	0	0	0		
8	4497	0		0	0	0	0	0	0	0		
	290909	10116	3	10116	0	0	0	0	0	0		

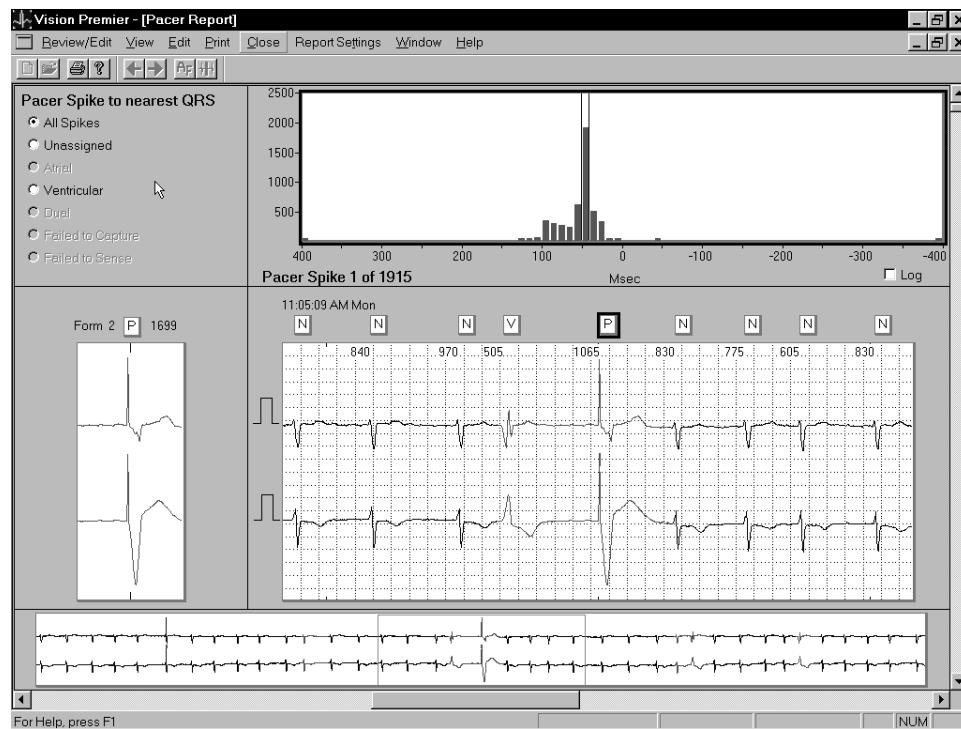
The total paced beats column indicates the sum of the atrial, ventricular, dual and operator paced beats. Beats classified as Failure to Sense, Failure to Capture and Failure to Fire are counted and tabulated hourly.

The operator can edit the counts for individual classifications. The totals are automatically computed after edits are made.

Pacer Review

This report is available to show you the relationship between the pacemaker spikes and any ventricular conduction or lack of ventricular conduction.

To access the pacer display page, click on the Review/Edit menu option, then click on the Pacer option.



Pacer Spike to Nearest QRS

This is the Pacer Spike to Nearest QRS view. On the left side of this screen, you have several options for which paced beats to view in this window.

- ✓ **All Spikes** - All pacer spikes to the closest QRS
- ✓ **Unassigned** - All pacer spikes that have not been assigned to a QRS
- ✓ **Atrial** - All pacer spikes that have been assigned to a QRS that has been identified as atrial paced
- ✓ **Ventricular** - All pacer spikes that have been assigned to a QRS that has been identified as ventricular paced.
- ✓ **Dual** - All pacer spikes that have been assigned to a QRS that has been identified as both atrial and ventricular paced (AV Sequenced Paced QRS).
- ✓ **Failure to Capture** - All instances in which the pacemaker triggered, but failed to cause a contraction
- ✓ **Failure to Sense** - Electrical impulse occurred, but was not detected by the pacemaker
- ✓ **Failure to Fire** - Pacemaker failed to activate

The histogram at the top of this window displays the number of pacer spikes which occurred at various intervals from the nearest QRS. Each bar in the histogram represents a 10msec duration. The zero in the center of the graph indicates the QRS. The height of each bar indicates the number of pacer spikes which have been detected at the indicated distance from the nearest QRS. The selected pacer spike is always shown in the center of the strip displayed in the middle of the window. The beat label is highlighted for the beat that is associated with the pacer spike.

The bars in the histogram display are colored coded for ease in identification. The colors are as follows:

- ✓ Unassigned - Green
- ✓ Atrial Paced - Magenta
- ✓ Ventricular Paced - Brown
- ✓ Failure to Capture - Blue
- ✓ Failure to Sense - Red

A right mouse click on one of the bars in the histogram displays a context menu from which you may edit the classification of all of the beats in that time frame to Atrial, Ventricular, Artifact, Failure to Capture or Failure to Sense.

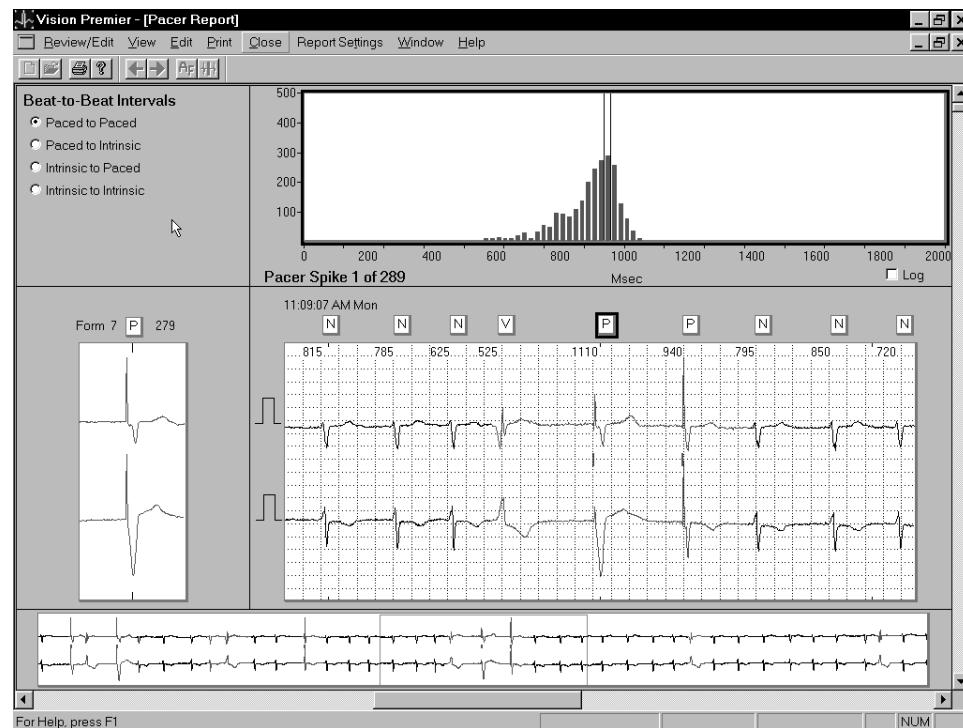


A right mouse click in the ECG strip in the middle of the window presents you with the option to insert that strip in the final report or to delete that ECG data. You may right click on the beat classification to change the classification for that particular beat.

The totals for all pacer spike classifications are automatically tabulated in the Pacer Summary page of the Final Report. Pacer spike classifications are encoded to the nearest appropriate QRS record. If you subsequently edit that QRS to artifact, it will also clear out the extended pacer classification information. If you edit a QRS from atrial or ventricular paced to some other beat label, that beat will no longer be counted as atrial or ventricular paced in the tabulation on the Pacer Summary page. Likewise, if you delete an ECG strip, any pacer spike in that strip will be removed from the tabulation.

Beat to Beat Intervals

To access the Beat to Beat Intervals display, click on the View menu option, then click on the Define Beat to Beat option.

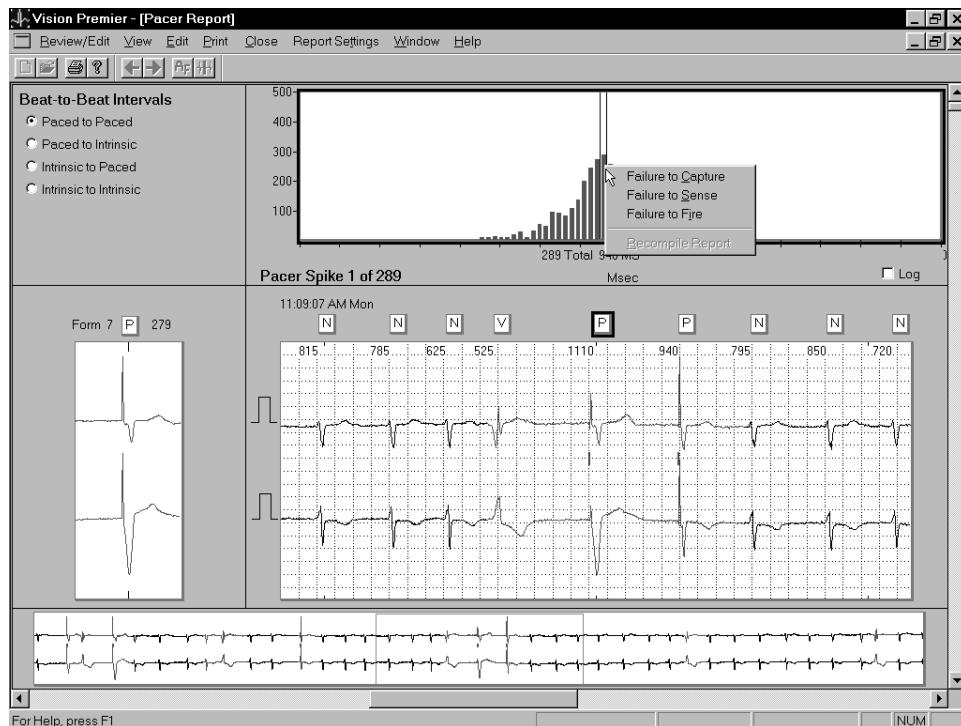


This display shows the distribution of the paced beat to paced beat RR intervals. On the left side of this screen, you have several options for which paced beat intervals to view in this window.

- ✓ Paced to Paced
- ✓ Paced to Intrinsic
- ✓ Intrinsic to Paced
- ✓ Intrinsic to Intrinsic

Each bar in the histogram display represents a 20msec duration. The selected beat is shown in the center of the strip displayed in the middle of the window.

A right mouse click on one of the bars in the histogram displays a context menu from which you may edit the classification of all of the beats in that time frame to Failure to Capture, Failure to Sense or Failure to Fire. The total number of beats in each category will be tabulated in the Pacer Summary page of the final report.



A right mouse click in the ECG strip in the middle of the window presents you with the option to insert that strip in the final report or to delete that ECG data. You may right click on the beat classification to change the classification for that particular beat.

Burdick, Inc., 500 Burdick Parkway, Deerfield, WI 53531 U.S.A. (608) 764-1919